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COMPULSORY LICENCING AND ACCESS TO MEDICINE

Dr. Sonika Bhardwaj Bhardwaj[1] & Aswathi Radhakrishnan[2]

I. ABSTRACT

At the time of the global pandemic, nations around the globe understood that a nation's true development is based on how well its healthcare sector performs or how well the distribution of access to medicine takes place. Big pharma companies produce patented, good-quality drugs, but the accessibility of these drugs is very limited, especially in the developing and least developing countries. Due to the patentability of medicines, the drug manufacturers will have an exclusive right over the product. Therefore, the cost of medicine in LDC(least developed countries) and DC(Developing countries) is too high. As an exception to this, a compulsory licence has been introduced. It basically allows the use of patented drugs or medicines to produce, use and sell even without the consent of the patentee or the inventor of the particular drug. Compulsory licensing could have a positive and a negative impact on society. The reason is that CL does help the LDC and DC with access to medicine in emergencies. On the other hand, the inventor's IPR right will be jeopardised. The CL will take away all the IPR protection under the patent law. This paper focuses on how CL plays a vital role in access to medicine, particularly in developing countries and also looks into how the CL addresses public health concerns.

II. KEYWORDS

Compulsory licensing, Developing countries, Least developing countries, access to medicine.

III. INTRODUCTION

The true development of one nation depends on how well the public health sector is? Access to medicine is a critical concern both developed and underdeveloped countries are trying to address. The big pharma companies or the developed countries that

[1] Associate Professor, Christ (Deemed to be) University
[2] LLM IPL, Christ (Deemed to be) University

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manufacture drugs have the potential to help other nations with the availability of essential medicine. The problem here is big pharma companies are trying to get a market exclusivity for their products to have an exclusive right over the drugs they developed.[3] This is how the companies make huge profit and create a monopoly by not allowing generic companies to enter into the market. The right to Patent is one of the IPR right available to the Patentee exclude others from making, selling or using a particular patented product. However, there is an exception under TRIPS and the Indian Patent Act, which is Compulsory licensing. It is where the government allows the use of patented products without the owner's consent. Compulsory licensing can only be granted under specific conditions for extreme public urgency, under any exceptional circumstances, in a national emergency, or even when the country is insufficient to manufacture sufficient pharmaceutical products.[4] The exception of compulsory licensing itself is a very debatable issue. During Covid, many developing and underdeveloped countries, including India had faced a shortage of medicines. Millions of people loved ones, and children have died due to lack of medicine. The supply of patented vaccines was limited because of their exclusive right. A practical solution by the Government at the time of crisis was the "Compulsory Licencing". During the crisis, a country like India was unprepared to produce millions of vaccines. Serum Institute of India and Bharath Biotech are the only two domestic firms produce 80-90 million dosages of vaccine.[5] Therefore it is clear that the supply of medicine are indeed an issue.

India and many developed and less developed countries have adopted the IPR system like copyrights, patents, and trademarks. The Introduction of IPR laws was not only for the protection of inventors but also from monopolies and restrictive trade practices. Today the Multinational corporations virtually dominate the entire globe by the tool of IPR monopoly. Foreign corporation does influence a lot in the DCs and LDC's; It is true that patent is one of the most significant tool in the IPR regime since it have variety of utility. Big pharma companies are the ones who benefit the most

[3] Prashant Reddy T, The Data Exclusivity Debate In India: Time For A Rethink?, 10 Ijlt (2014) 8
[4] Indian Patent and Designs Act
[5] Oshmi Jaiswal, Compulsory Licensing: A Viable Solution for India to Override the Covid Vaccine Patents Domestically, 1.4 JCLJ (2021) 316

from data exclusivity. The patenting power helps these companies to profit out of market exclusivity. Therefore, around the globe the drug patenting has been criticised everywhere. The major reasons behind these are privatizing the drugs in the name of public health, huge price hikes for medicines in developed countries, and lack of supply of generic medicine in developing countries. Inventor companies have looked at data exclusivity as a solution for predatory pricing, which gives them access to market exclusivity indirectly. [6]

Is it necessary to protect data exclusivity in India? Since India doesn't have any laws about it. Before focusing on data exclusivity as such it is needed to look into what is the purpose of IPR in general. The purpose of IPR itself is to protect the creation of owners from being exploited or misused. When it comes to the big pharma companies, they are investing a huge amount in R&D and clinical trials; since their data is not being protected, the generic companies are able to use the data and manufacture the same without any effort. Article 39(3) does cover the unfair commercial use of if, but to what extent? Without the prior consent of inventor companies, the generic companies cannot use the drugs, but it's not the case; when it comes to the public interest at large, the generic company wins. Unfortunately, in India, the generic companies are literally taking advantage of inventor companies. These companies invest in, research, and conduct clinical trials and then get approval from regulatory bodies.

In India, in 2012, a landmark decision where the court allowed compulsory licensing to market generic versions of medicine for cancer treatment. The drug was patented by the German drug maker Bayer AG, and it was treated for liver and Kidney Cancer at a cost of Rs. 2.8 lakhs. Nacto Pvt. Ltd, another pharma company, had applied to manufacture the same medicine, but it was rejected. Later on, the Indian Pharma company applied for compulsory licensing, stating that Bayer had failed to meet the local market's needs. The court looked into factors like how many people were affected, the cost of the medicine in the market and whether these factors affected the

[6] The Significance of the Data Exclusivity Debate and its Impact on Generic Drugs, Srividhya Ragavan,(2017) 1.1 JIPS 131

accessibility of medicine. The court also looked into section 84 of the Patent Act, which states that after three years of granting a patent, any entity can apply to sell generic drugs, where those patented drugs were not available to the public at a reasonable price.

If we look into why countries should provide compulsory licensing as an exception? It is literally going against the IP rights available to the inventor. The only reason for compulsory licensing is that it is to increase the accessibility of medicines or life-saving drugs. Many developed countries do not want compulsory licensing because the countries have big MNCs that produce and import medicines. If the market is exclusive for them, they can make more profit. This paper focuses on the meaning of Compulsory licensing in the statutory provisions and in the TRIPS agreement and explains why Compulsory licensing faces certain complexities. It addresses how the monopoly right and the parallel import affect the access to medicine. In the concluding part, this paper points out the importance of compulsory licensing in India.

IV. LEGAL PROVISIONS FOR COMPULSORY LICENSING

When it comes to the legal provisions pertaining to the Compulsory licence, it is necessary to understand the need for a Patent. A patent is one of the Intellectual Property rights where the inventor or the person who originally invented a particular product will have an exclusive right to prevent others from manufacturing, selling or even using it. The WIPO (World Intellectual Property Organization) defines this, and the prime limit for patent protection is a period of 20 years. The purpose of patenting or any IP is to encourage the inventors by protecting their rights.[7] Compulsory licensing of the other hand where the government will allow the third party to manufacture, sell and use the patented product without the consent of patent owner.

Under section 84, Chapter XVI of the Indian Patent Act 19708,[9] explains compulsory license. For the application of Compulsory licence, an interested person can make an application to the Controller after three years of granting a patent. To file compulsory

[7] https://www.wipo.int/patents/en/
[8] Indian Patent Act, 1970
[9] Indian Patent Act, 1970

licensing there are certain conditions like: *Firstly*, Failure to Meet Reasonable Requirements of the Public at Large: This explains a situation where the patent holder is unable or unwilling to meet the demand for a particular product or service that is considered essential for the well-being of the public. In cases where the patent holder is not adequately supplying the market to fulfil the reasonable requirements of the public, a country's patent law may allow for the issuance of a compulsory license. *Secondly*, The inaccessibility of the Patented Invention at a Reasonably Affordable Cost to the Public: The ground for compulsory licensing arises when the patented invention is not available to the public at a price that is considered reasonable and affordable. Suppose the cost of the patented product is prohibitively high. In that case, it may be deemed as a barrier to access, and a compulsory license could be granted to allow other entities to produce the same product at a more affordable price. *Thirdly*, Non-Working of the Patented Invention in the Indian Territory: If a patented invention is not being commercially worked or produced in the territory of India, it may be a ground for the grant of a compulsory license.[10] This means that the patent holder is not making efforts to utilize the patented technology within the country, and this non-working can be considered detrimental to the public interest.

Under the Indian Patents Act, the Controller of Patents has the authority to grant compulsory licenses based on these and other grounds. It is important to note that any decision to issue a compulsory license is usually subject to careful consideration of the specific circumstances and a balance between protecting the patent holder's interests and addressing the public health needs and welfare. These provisions are aligned with the flexibilities provided by the TRIPS Agreement to ensure that countries can take measures to protect public health and access to medicines. Compulsory licensing is a delicate balance between safeguarding intellectual property rights and addressing the broader societal needs, particularly in public health.

Similarly, under section 92 and section 100 of the Indian Patent Act explains the provisions relating to the patent protection under certain circumstances. Compulsory

[10] Oshmi Jaiswal, Compulsory Licensing: A Viable Solution for India to Override the Covid Vaccine Patents Domestically, 1.4 JCLJ (2021) 316

licensing can be issued by the Patent Controller in *suo motu* when the notice issued by the Central Government under the following circumstances like National emergency, Public Non-commercial use and in case of extremely urgent requirements. This has been explained in section 92 of the Indian Patent Act of 1970. Under section 100, the government can authorize the use of the patented product or any inventions. The inventor will be receiving a reasonable royalty.

The Statutory provisions under the Indian Patent Act and in the TRIPS, agreement explain the necessity of Compulsory licensing. It is essential to focus on improving the accessibility of medicine in a cost-effective mechanism. But this is only applicable only in case of emergencies. So many people will lose their lives without proper medication because of the huge price. It is also essential to understand what contributes emergencies and whether is it necessary to wait and watch people die.

V. TRIPS AND COMPULSORY LICENSING

It is essential to focus on Compliance with International Agreements. The relationship between international agreements and domestic laws, emphasising that any treaty or convention conflicting with domestic law will be void unless given effect under Article 253 of the Indian Constitution. This highlights the importance of domestic implementation of international agreements to make them legally binding. When it comes to the Patent Law and Access to Medicines, The Novartis case raised questions about the rationality of patenting and pricing of medicines. It is noted that pharmaceutical companies often seek to extend patent protection through incremental innovations, impacting access to drugs, especially in developing countries. This raises concerns about the balance between patent rights and public access to essential medicines. TRIPs Agreement and Indian Patent Law. The implications of the TRIPs agreement on the Indian Patents Act 2005. It mentions that the Patents (Amendment) Act, 2005 was passed to comply with TRIPs obligations, introducing the product patent system in India for the first time. This reflects India's efforts to align its patent laws with international standards. Sovereignty and Patent Monopoly: The document discusses the impact of international agreements on national sovereignty, particularly in the context of the TRIPs Agreement. Critics argue that India's sovereignty has been

curtailed by acceding to the TRIPs Agreement, raising concerns about the influence of international corporate power. This highlights the tension between international obligations and national sovereignty. Patentability and TRIPs Agreement: the concept of patentability under the TRIPs Agreement and Section 3(d)[11] of the Indian Patents (Amendment) Act, 2005. It emphasises the need for countries to carefully consider economic, legal, and ethical aspects when implementing Article 27(1) of the TRIPs Agreement[12]. This underscores the importance of balancing patent rights with public interest. Judgment of the Madras High Court[13]. The document provides insights into the Madras High Court judgment on the Novartis case. It discusses the arguments presented regarding the inconsistency of Section 3(d) with the TRIPs Agreement and its potential violation of the Indian Constitution. This highlights the legal complexities and jurisdictional issues involved in adjudicating conflicts between domestic laws and international agreements. In summary, the provided excerpts offer a comprehensive analysis of the Novartis case, shedding light on the intersection of international law, patent rights, and public access to essential medicines in the context of the Indian Patents Act and the TRIPs Agreement.[14] Under Article 31 of the TRIPS agreement provide conditions for issuing CL.

It is important to understand that the patentee will have an exclusive right over the particular product he/she invented. But it does not mean the right holder is entitled to do whatever he or she desires. To be specific, when a right is granted to the patent holder, then he shall expected to fulfil certain obligations. If the patentee is not meeting the expected obligations, then it will be considered to be an unfair exploitation of IPR privilege. By looking into the history of Compulsory licensing is more than a century old. It has had a huge impact on the TRIPS platform. The Paris Convention on Industrial Property 1883 under Article 5A mentioned the concept of CL. It states that to grant CL to prevent the abuse of patent rights. CL was critical in

[11] Indian Patent Act 1970

[12]https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm#:~:text=Article%2031(f)%20of%20the,is%20made%20under%20compulsory%20licence.

[13] Novartis v. Union of India & Others [2013] 13 S.C.R. 148

[14]Interpretation Of Section 3(D) In The Indian Patents Act 2005: A Case Study Of Novartis, K.D. Raju, 1 IJIPL (2008)

Patent law, and developed countries like the UK, Canada, and the US used this abundantly by stating the government can use the patent for at most any public purpose. Initially, in the US, the government had the authority to use patented resources even without notifying the patentee that only the right to remuneration was available to them.[15] After the formation of TRIPS, the price of patented pharmaceutical products became high, leading to difficulty in access to medicine.

Compulsory licencing, by its nature, is facing certain complexities, which are :

1. The concept has not emerged from one particular land.
2. It is not governed by one set of laws rather than it has been governed by both international and domestic laws directly and indirectly.
3. Since it is governed by national and international; these set of laws have diverse objectives. Although international regulations led to the development of national laws regulations, it impose a very restrictive guidelines as compared to the International laws.
4. Different countries have different policy objectives with respect to the IPR laws, public health policies etc.
5. The nature of the state itself is different form country to country, with respect to its industry, economy, life style, availability of resources etc. Some countries are prone to diseases and some are having different birth and death rates.
6. Constant pressure from developed nations. Most developed nations provide external aid for the developed or least developed nations. Therefore, it creates pressure for least and developing countries to create a legal framework favouring the developed nations.
7. One of the complicated issues is the influence of the US in interpreting the TRIPS agreement. According to US way of Interpreting is that the IP holder are free to decide how to work their invention. Patentee is not obliged to any social responsibility even they are benefiting from the society.

[15] Institute of Patent and Trade Mark Attorneys, Australia Submission to Advisory Council on Intellectual Property Discussion Paper review of Crown Use Provision in Patents and Design Legislation: Last accessed on 20th June 2011 http://www.acip.gov.au/crownsubs/IPTA.pdf

Compulsory licensing has its complexities. Similarly, it has a considerable impact not only in developed countries but also in the developed nations. The situation and magnitude of CL varies from nation to nation.[16] The right to determine the nature of CL solely depends upon the individual nations. The developed nations' perspective of CL may change from time to time depending on the emergency. All these factors make this subject even more complex.

VI. MONOPOLY RIGHT

It IPR and competition law have very common objectives. Like economic expansion, technological progress and consumer welfare. To be specific, IPR focus on innovation and introduction of new products in the market. Competition law, on the other hand, promotes consumer welfare by providing quality products and maintaining the same. The IP does have a monopoly right, and it is unchanged. There are two aspects of monopoly in the IP, one which rewards the inventor for his or her efforts. The inventor also has a right to protect it from others using, selling or manufacturing it. The second aspect is that the monopoly which grated for the benefit of the people.[17] Therefore, the owner can enjoy the monopoly right under IPR. The concerning issue is when there is a misuse of monopoly; it will lead to trade restriction and jeopardize technological advancement and industrial progression, which will affect the public interest and consumer welfare. The patentee has an "*exclusivity*" right over the product he or she has created; this itself is a very debatable issue because the exclusivity over a particular product will create a monopoly, which will make the people and the economy suffer. When we look into the aspect of lack of medicine due to monopolizing the drugs, it will have a negative impact on the health of the general public. So, it is necessary for the patentee to look into the interest of the public at large rather than profit.

The Patent is not granted for the benefit of patentees alone rather than it is for the people when it is needed. The component or the condition to grant a patent is very

[16] Milind V. Sathe, Compulsory licensing in Knowledge Economy -It is now or never- What, why and when about CL, Compulsory licensing? Past and present

[17] Abhipsita Kundu* and Dipayan Bhattacherjee, Owners 'Right Versus Owners' Monopoly: The Ipr-Competition Interface, CNLU LJ (3) [2013] 57

critical because the patented product could or will have the ability to boost the development of that particular industry only if the patented product worked in the country. So, after the implementation of TRIPS, patented products can be imported in any part of the world. Therefore, it has paved the way for an authentic way of centralizing industry in specific countries. Now, what is happening is that not only has industrial development been denied, but also the skill set, discussion of technologies, etc.

Post TRIPS, the impact of patenting is different because it has diminished the spread of knowledge and growth of developing and least developed countries as well.[18] The only solution available to it is that the national laws should make it clear that the granting of the patent to work the invention within the country and to enjoy the monopoly also to determine that the patentee interprets the grant of patent 'only' for importation.

In case of emergencies, the nation has to decide whether monopoly right and the IPR holder is of primary importance when it comes to safeguarding the interest of its subject. When issues threaten social tranquillity, public peace, and the safety and security of the nation, it is dangerous to continue to honour the IP right holder and the IP monopolies. That is the nation adopted Compulsory licensing.

VII. ACCESS TO MEDICINE

Health care is one of the issues of concern around the globe. Every country must have proper access to medicine in case of necessity. Most developing and least developed countries have huge populations; practically, it is challenging to give advanced health care. The AIDS epidemic is one of the major worldwide problems. All the healthcare concerns cannot be solely addressed in terms of pharmaceuticals. The other factors like (a) socio-political conditions, (b) financial burdens, (c) physical factors, (d) focus on the economic policies, (e)information asymmetries and (f) the cost and health care goods and services in a particular country.

[18] Milind V. Sathe, Compulsory licensing in Knowledge Economy-It is Now or Never- What, Why, and When about CL, What is Patent Pg. 25,26

Compulsory licensing may not improve access to health care or provide essential medicines, but it does help pursue further opportunities in economic interest where the product will be available to people in developing countries. When a developing country has availability to medicine, it is often considered to be ineffective or even harmful because of the quality of the product available. For example, counterfeit medicine[19] is available on the market; this issue exists under the concept of compulsory licensing.[20] The price of the product is the main problem in accessing medicines. The underdeveloped and developing countries do not have the technological facilities or industries to produce such quality medicines, so they end up paying more. The developed nations have better law enforcement, and those nations will always prioritize the public interest.

VIII. PARALLEL IMPORT

Parallel importation is a consequence of the "exhaustion of right" or "doctrine of first sale," asserting that after the initial authorised sale of a physical item, the intellectual property owner has been adequately compensated, leading to the exhaustion of some or all exclusionary rights related to that item. This phenomenon results in parallel imports when a product lawfully marketed under an intellectual property (IP) regime in one country (X) is imported into another country (Y) without the approval of Y's corresponding IP holder. Parallel imports involve goods produced legitimately under copyright, patent, or trademark protection in one market and subsequently imported into another without the local owner's authorization. While parallel importation can occur in various forms of intellectual property rights (IPR), it particularly affects patent and trademark rights in the case of pharmaceutical products.

The economic driver for parallel importation lies in the price disparities between markets arising from the practices of IP rights holders establishing segmented international markets. This practice allows them to set different prices in different markets, potentially eroding their profits from international sales. Additionally,

[19] https://www.wipo.int/edocs/pubdocs/en/wipo_pub_628_2020
[20] Richard P. Rozek, The Effects of Compulsory Licensing on Innovation and Access to Health Care, 3 J. World Intell. Prop. 889 (2000).

specific national price regulations contribute to the market price differences. Parallel importation arises when the cost variations between countries exceed the costs associated with selling and transporting goods across borders.

In the US, the concept of parallel import has a different approach, where the companies cannot prevent customers from re-selling the goods within US territory. It also works against the market power arising from private exclusive territories. Due to the emergence of e-commerce businesses, the access to branded drugs increases at a lower price. Similarly, in the case of Japan, it also allows the patented parallel import goods, but it has to comply with the foreign price regulations. Australia has a different approach when it comes to parallel import.[21] Parallel imports are permitted in the case of patented drugs, but the patent owner can block the import. Therefore, consumers cannot benefit from the availability of cheaper medicine.

According to Maskus, parallel importation benefits consumers by expanding competition, leading to lower prices. However, there are drawbacks, including resource wastage through the cross-hauling of goods between countries. Another concern is that allowing parallel importation might increase the trade in counterfeit and pirated goods, leading to consumer deception.[22] Importantly, the TRIPS Agreement does not establish global norms on the legality of parallel importation, making it a matter of domestic legal consideration. Countries can choose between national, international, or regional exhaustion systems. The international exhaustion doctrine permits parallel trade, while the national exhaustion restricts it. Countries aiming to enhance access to medicines may opt for international exhaustion, enabling the importation of medicines from anywhere globally and retailing them at more affordable prices than in their own country.

IX. CONCLUSION

[21] Keith E. Maskus, Parallel Imports In Pharmaceuticals: Implications For Competition And Prices In Developing Countries, Final Report to World Intellectual Property Organization, (2001)
[22] Keith E. Maskus, Parallel *Imports*, 23 The World Economy, 1269 (2000), 1271

Compulsory licensing is indeed an effective solution for access to medicine but to what extent. This paper tries to address both the positive and negative sides of it. Points needed to be considered is that:

1. The price of medicine for the patented drugs is considerably huge. In developing or least developing countries, people need access to these medicines. Therefore, Compulsory licensing is indeed a problem solver in many aspects, but the quality of the product is still in question.
2. The national and international perspectives on compulsory licensing are different. TRIPS address the IPR concerns at the International level, and member countries are bound to follow the same. The issue arises when developing countries face health crises, and then, with the help of CL, a country can access medicine. So, CL does affect the patentee's right of exclusivity. When it comes to patentee rights or national emergencies, in the case of public health, the nation will only focus on its people rather than an individual's rights.
3. Multinational companies always disagree with the concept of CL because they invest huge amounts in R&D, so they also expect a huge return. From a Patentee's point of view, they should have the upper hand for their invention. As stated above, when it comes to national importance, collective rights is always considered.

Compulsory licensing is always considered as an instrument for protecting the public interest. There are many challenges when it comes to the IPR protection regime. Essential drugs provided by the WHO have Patent protection. It is necessary to understand that only a financially weak society can afford generic medicine, not patented products. The price of Patented drugs is so high that a common person might lose hope in their life itself. So, it is our nation's duty to prioritize public health over individual rights. The debatable issue is whether patent protection or the public interest must be protected in case of an emergency. Compulsory licensing is always a domestic legislative framework with its own territorial boundaries. It is also necessary that compulsory licensing be protected because a country like India does not have advanced healthcare facilities like in any other developed country. Since the

population of India is so high, the availability of medicine also needs to be high. The only restricting factor here is the price of the medicine. Under the Indian Constitution, the right to life also includes the right to adequate health care. Therefore, in this country, the primary importance is for the well-being of the citizens.